

Community Engagement in *Moral Science*: *Protecting Participants in Human Subjects Research*

Contents

I. Introduction	1
II. Learning Objectives	1
III. Background	2
IV. Reading	4
V. Discussion Questions	4
VI. Problem-Based Learning	8
VII. Exercises.....	11
VIII. Glossary of Terms.....	12
IX. Additional Resources.....	13

I. Introduction

In *Moral Science: Protecting Participants in Human Subjects Research (Moral Science)*, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) assessed contemporary standards for protecting individuals participating in research.¹ In this report, the Bioethics Commission examined many aspects of human subjects research protections, including community engagement, and made recommendations for improving the current system.

II. Learning Objectives

Students should be able to:

1. Discuss the benefits, challenges, and ethical reasons to conduct community-engaged research.
2. Understand and discuss the differences between community engagement, community consent, and informed consent and be able to apply each concept appropriately in reference to a given research project under consideration.

¹ Presidential Commission for the Study of Bioethical Issues (PCSB). (2011, December). *Moral Science: Protecting Participants in Human Subjects Research*. Washington, DC: PCSBI.

3. Consider different means by which to engage communities in domestic and international research and how to determine the desired level of engagement in research.

III. Background

Much of the groundwork for community engagement in research has been established in international settings, in which host countries and communities work with foreign researchers to initiate and conduct research. This model has been adapted across a wide array of international and domestic research environments. One of the Bioethics Commission's 14 recommendations in *Moral Science* focused on improving the current system for protecting participants in research through community engagement.

Recommendation 9: Promote Community Engagement

The federal government, through the Office for Human Research Protections and authorized research funders, should support further evaluation and specification of the Joint United Nations Programme on HIV/AIDS and the AVAC *Good Participatory Practice Guidelines* with the aim of providing a standardized framework for those community engagement practices that would further the protection and ethical treatment of human subjects in all areas of research. Research should be conducted to prospectively evaluate the effectiveness of this framework and strengthen it after it is developed.²

As part of its analysis and deliberative process, the Bioethics Commission convened a subcommittee of international experts in bioethics and biomedical research. This subcommittee, the International Research Panel, published its proceedings in 2011, *Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues*, in which it advised the Bioethics Commission on the “effectiveness of current U.S. rules and international standards for the protections of human subjects in scientific studies supported by the U.S. Government.”³ Although the International Research Panel's findings and recommendations are not the Bioethics Commission's recommendations, their work informed the Bioethics Commission's final recommendations to the President in *Moral Science*.

² Ibid, p. 82; “The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and social-behavioral research.” HHS. (n.d.). About OHRP: Mission [Webpage]. Retrieved from <http://www.hhs.gov/ohrp/about/mission/index.html>.

³ The International Research Panel of the Presidential Commission for the Study of Bioethical Issues (PCSBI). (2011, September). *Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues*. Washington, DC: PCSBI, p. ii.

One of the International Research Panel's findings states:

Community engagement is important to (i) demonstrate respect for host and collaborative communities by engaging them as partners in research, (ii) enhance understanding of how U.S. standards can be applied in other cultural contexts, and (iii) provide opportunities for ongoing oversight and monitoring of research activities. Community engagement can consist of a broad spectrum of activities, such as community consultation, inclusion of lay community members on ethics review boards, and the formation of community advisory boards. Community engagement can be especially important to build trust or close the gap in power differentials between those conducting or sponsoring the research and the community. But community engagement is not a sufficient guarantor of ethical research, and it is a complement to, but not a substitute for, basic human subjects protection systems.⁴

The International Research Panel's first recommendation to the Bioethics Commission states:

Researchers must demonstrate respect for human subjects and their communities in all phases of clinical trial design and implementation. Recognizing other cultural standards and practices through community engagement is one concrete means of showing respect. In addition to ensuring that the standard safeguards for human subjects in research are in place—such as obtaining informed consent, minimizing risk, and conducting independent review—researchers should engage with communities or populations to be involved in the research. This engagement provides not only a local mechanism of accountability, but also a partnership in achieving the research goals. There is an emerging literature and global conversation concerning the means by which to properly engage communities. Open and inclusive dialogue is crucial to showing respect for communities, learning about context, responding to concerns, and working toward effective capacity building. Community engagement can strengthen and facilitate research while protecting subjects. For example, in a community in which written informed consent is considered inappropriate because of confidentiality issues, adherence to local traditions, or distrust of the signing process, researchers can explore together with the community other more acceptable methods of documenting informed consent that will meet regulatory requirements while respecting local norms. Nonetheless, researchers cannot—and should not—accept uncritically everything that a community recommends or requests. Cultural standards and practices should be followed only to the extent that they do not conflict with basic universally recognized human rights. For example, some paternalistic cultures designate certain individuals to speak on

⁴ Ibid, p.7.

behalf of the community. Although they may be important representatives of community interests, it cannot be assumed that they are always acting on behalf of individuals' rights and welfare.⁵

IV. Reading

For the purposes of discussion, have students download and read the following Bioethics Commission materials (reports can be found on the Bioethics Commission's website at www.bioethics.gov under "Projects"):

Moral Science: Protecting Participants in Human Subjects Research, pp. 78-82 ("Promoting Community Engagement").

Also on the *Moral Science* page of the Bioethics Commission's website:

Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues, pp. 36-40 ("Session 2: Respecting Diversity and Community Engagement").

V. Discussion Questions

The following questions are based on the information provided above and through the indicated reading and are intended to reinforce important aspects of research-related community engagement that are highlighted in the Bioethics Commission's *Moral Science* report and the International Research Panel's published proceedings. Important points are noted with each question to help the instructor guide a group discussion. The "Additional Resources" section will be helpful in answering these questions.

- 1. One understanding of community engagement calls for communities and researchers to function as equal partners throughout the research process. What potential challenges might this raise and how might those challenges be overcome?**

Starting points for discussion:

- a. *Example challenge*: Tension between scientific and community values.

Example resolution: Researchers must communicate the rationale for specific experimental design decisions, for example, the parts of a protocol that are essential to answer the questions being asked and be willing to consider and incorporate community needs as much as possible when designing protocols.

⁵ Ibid, p.8.

- b. *Example challenge:* Tension between scientific expertise and community-specific forms of knowledge.

Example resolution: As part of relationship building, both researchers and community members should work to outline and share their particular knowledge and perspectives. Likewise, both parties also have a responsibility to accept the knowledge and expertise of the other in order to collaborate in a productive way.

2. What are the potential benefits of integrating community norms, beliefs, values, and cultural sensitivities into research activities? How might these potential benefits accrue to the community and/or the research or scientific community? Are there any challenges or drawbacks to doing this?

Starting points for discussion:

- a. *Benefits to community:* Research addresses community needs and concerns; community values are respected and reflected in research design; community members are more likely to feel comfortable participating.
- b. *Benefits to scientific community:* Community acceptance often leads to higher rates of participation; respectful incorporation of the community can lead to community feedback, generating the potential for more effective research designs and follow-up research.
- c. *Challenges:* This sort of interaction requires a greater time commitment (time to build a relationship of mutual trust).

3. The International Research Panel asserted that community engagement demonstrates respect for cultural differences, which is compatible with the ethical conduct of human subjects research. What ethical principles underlie this assertion and how does community engagement support these principles? (Note to instructor: ethical principles that support community engagement are addressed in the Community Engagement: Background module.)

Starting points for discussion:

- a. *Respect for persons:* Community engagement supports the ethical principle of respect for persons in that it invites individuals and community representatives to share their collective views, values, and beliefs in shaping the direction of the research. Participation in this manner respects communities and their members by allowing the research design, recruitment strategies, and analysis to integrate community-specific concerns and considerations.

- b. *Beneficence*: Community engagement supports the principle of beneficence by encouraging community members to help direct and structure research efforts to address a need within the community rather than a more generic need of another possibly unrelated population.
 - c. *Justice*: Community engagement supports justice when community input identifies vulnerable populations or disenfranchised groups that researchers might otherwise overlook. Identifying these groups gives researchers an opportunity to engage them, ensure that research risks do not fall disproportionately to any one group, and ensure that benefits of research are fairly distributed throughout the community.
4. **The International Research Panel points out that researchers should not uncritically accept everything that a community requests. Why is this so? What other examples might apply, aside from the consent issue highlighted in the International Research Panel's recommendation to the Bioethics Commission (see Section III. Background, above)?**

Starting points for discussion:

It is important to respect local customs, but they cannot be incorporated in the research project if they impinge on essential protections of research participants. For example:

- i. Respect for an individual's autonomy must be maintained. As in the example provided in the International Research Panel's recommendation, individual informed consent must be obtained and cannot be supplanted by community consent.
- ii. Intentional harm must not be done to any individual, as specified by the principle of non-maleficence (the corollary to the principle of beneficence), even if it were to benefit the greater community.
- iii. The principle of justice requires that the burdens and potential benefits of research be fairly distributed. No group within a community should be unfairly singled out (based on factors irrelevant to the study) to bear the burden of research. Likewise, if research results in a beneficial intervention, community members should have fair access to the intervention.
- iv. Scientifically valid research design is essential to ethical human subjects research. Research that exposes persons to risk of harm when there is no possibility of valid results is unethical.

**5. What is community consent and how does it relate to individual informed consent?
How might researchers address the need to obtain both forms of consent without the
two coming into conflict with each other?**

Starting points for discussion:

- a. *Community consent*: Consent given by community leaders that pertains to all members of the community rather than consent given by an individual.
- b. *Informed consent*: Consent given by an individual to participate in research or undergo a procedure after receiving and understanding the relevant facts about their participation (e.g., risks, benefits, potential alternatives).

Note that community consent can supplement but cannot substitute for individual informed consent.

- c. *Possible reconciliation*: In some cases, researchers might seek community consent prior to recruitment, in which they must then obtain individual informed consent from participants. When the community is engaged, community consent is less of a hurdle due to the integration of community norms and values in research design.

**6. Community engagement can be important in both domestic and international research.
How might the approaches differ from the researchers' point of view?**

Starting points for discussion:

- a. The need to engage community representatives in international research might seem more apparent due to researchers' unfamiliarity with the local culture and the additional need to seek out information on local regulations and legal restrictions on research.
- b. Researchers might assume some baseline cultural understanding of community values when conducting domestic research and have familiarity with regulatory requirements. Despite some level of familiarity, researchers should approach community engagement for domestic research in a similar way, remaining open to input from the community since it is unlikely that they are deeply familiar with the intricacies of cultural variation that exist in smaller communities, even within researchers' own country.

7. How might researchers approach community engagement when working with a community that employs a significantly different ethical framework than that of the researchers' own culture?

Starting points for discussion:

- a. Researchers must invest time in learning about the community with which they plan to engage. Community leaders should be identified and communications should be initiated with them to begin the engagement process. Community advisory boards and local ethics committees can be consulted in the design of research as well.

VI. Problem-Based Learning

Some examples of Community Engagement are described in Principles of Community Engagement, Second Edition. For scenarios A-C (below), examples can be found in:

Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement, Second Edition*. Bethesda, MD: National Institutes of Health (NIH). Retrieved from [http:// www.atsdr.cdc.gov/communityengagement/](http://www.atsdr.cdc.gov/communityengagement/).

Scenario A. Project SuGAR (Sea Island Genetic African American Family Registry)⁶

Researchers worked with the Gullah-speaking African American population, a geographically isolated group in South Carolina, to learn about their genetic makeup as it relates to the prevalence of diabetes in this community. The project involved community-based participatory research as well as a community-health outreach component. The list of services provided to the community included health education and cultural fairs, health screening, project-related employment, and development of a lasting citizen advisory committee.

1. How did the development of the citizens' advisory committee (CAC) result in the empowerment of the community and the creation of a "research-positive" community?

Starting points for discussion:

- a. The CAC was involved in all stages of the research and made sure that the research design was sensitive to the cultural and ethnic background of the community.

⁶ Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement, Second Edition*. Bethesda, MD: National Institutes of Health (NIH). Retrieved from <http://www.atsdr.cdc.gov/communityengagement/>.

2. What challenges must researchers address when working with an isolated community?

Starting points for discussion:

- a. Developing a relationship with and gaining trust of the community;
- b. Learning about the history and culture of the community and any factions within the community.

3. How did the researchers engage in capacity building with the community?

Starting points for discussion:

- a. Researchers provided services to the community including health education fairs, health screenings, and employment for community members as staff on the research project.

4. Why is capacity building important in relation to community engagement?

Starting points for discussion:

- a. Capacity building demonstrates respect for the community, an extension of the ethical principle of respect for persons, and establishes a strong foundation upon which to build a trusting relationship with the community.

Scenario B. Formando Nuestro Futuro/Shaping Our Future⁷

Researchers used a multi-methods approach to learn about type 2 diabetes in a Hispanic farmworker population in Idaho and their families in Mexico. The project involved in-home education of participants that was personalized for families and evolved over several visits as a result of the family's input.

1. How might the ethnographic methods used have contributed to the positive response to the research from the community?⁸

Starting points for discussion:

- a. The ethnographic study enabled researchers to become familiar with both communities in Idaho and Mexico and further understand how families were split between the two nations and communities. Expending the time and effort to

⁷ Ibid, p. 73.

⁸ Ethnographic research uses a qualitative research design aimed at exploring cultural phenomena.

understand these factors and build relationships with the communities might have engendered the trust and cooperation of these families.

2. Why would having a bilingual and bicultural research team be best for this type of research?

Starting points for discussion:

- a. The families involved were split between two countries and therefore were affected by multiple cultural influences. Employing a bilingual and bicultural research team was important in this research because it meant that community members were included as more than participants; communities participated in research design and helped to work with the results to develop specialized educational tools for each family.

Scenario C. Improving American Indian Cancer Surveillance and Data Reporting in Wisconsin⁹

Spirit of EAGLES, “a program funded by the National Cancer Institute to address comprehensive cancer control through partnerships with American Indian communities,” conducted cancer surveillance research with nine partner organizations affiliated with American Indian tribes.¹⁰ Partner organizations were provided with funding, community-specific cancer surveillance data, and decision-making power during the design phase of the research.

1. Discuss the importance and challenges of sharing data with research participants.

Starting points for discussion:

- a. The return of raw data to local clinics and directors for interpretation helped to deepen trust between communities and researchers and eventually led to community-specific cancer interventions.
- b. Data sharing can be challenging in that it requires bidirectional trust and ongoing collaboration to ensure that data analysis between sites is compatible.

2. What can researchers do before engaging in research with populations that historically harbor mistrust of medical research?

Starting points for discussion:

- a. Researchers first have to acknowledge the history of mistrust.

⁹ Ibid, p. 75.

¹⁰ Ibid, p. 75.

- b. Researchers must then address the root of that mistrust by including the community in the process of research planning and design from the beginning of the project.
 - c. Prioritizing the needs of the community and continuing to include community insight and participation throughout the project might help to rebuild trust that was lost in the past.
- 3. Discuss the importance of community engagement in the planning phase of research. What basic concepts regarding methodology need to be communicated so that all parties involved share a common terminology? How much latitude can and should be granted to members of the community to determine the line of inquiry pursued or which methods are employed?**

Starting points for discussion:

- a. In a multi-site research study such as this, the communities must be included in the planning phase. In this early phase, different viewpoints can be discussed and research design can be negotiated in a way that is inclusive of all groups. A common terminology is important to the success of a multi-site study so that data can eventually be combined for overarching analyses.
- b. Once baseline terminology is set and data requirements determined, individual sites can have the option to conduct additional research on their datasets after the group analysis is complete, as occurred in this case.

VII. Exercises

Exercise A. *During the Bioethics Commission's fifth public meeting in August 2011, Dr. Connie Celum presented current and historical practices of international human subjects research. In her remarks, she highlighted a particular study funded by the Gates Foundation, which employed approximately 3,400 African couples in studies regarding herpes transmission. Transcripts and archived webcast video of Dr. Celum's presentation can be found on the Bioethics Commission website (Meeting 5, Session 2). Have students watch Dr. Celum's presentation (beginning at 01:23 on the webcast video) and discuss the following:*

- 1. Dr. Celum highlights considerations that are of particular importance when conducting research in developing countries. What are some of these considerations and how might they affect how researchers engage the community during research studies?**

- a. *Stigma associated with poverty*: Community members and potential research participants might be wary of foreign researchers who are unfamiliar with their personal hardship. This disconnect might prevent researchers from establishing a trusting relationship with the community, which is essential to proper communication and ethical research design.
- b. *Limited or no access to health care*: Once a study is completed, potential participants might have difficulty accessing the medical services needed to benefit from an intervention shown to be beneficial as a result of the research. What duty might researchers have to provide participants access to therapies that prove beneficial?
- c. *Poor education*: Researchers must be careful to communicate with community members at a level they can understand. As Dr. Celum emphasizes, it is unreasonable to expect potential participants with limited education to understand lengthy or technical consent forms.

VIII. Glossary of Terms

Autonomy: The capacity to direct the course of one's own life or to live according to one's own values and beliefs.

Beneficence: An obligation on the part of researchers to undertake efforts to maximize possible benefits and minimize potential harms to research participants.

Capacity building: Involving a local community in the research process with the goal of strengthening skills, competencies, and sometimes infrastructure to overcome existing social and/or economic barriers.

Community-based participatory research: Research in which the community helps to identify the topic or issue to be studied based on local priorities, actively participates in developing the study design, and provides guidance to the researchers regarding participant recruitment and retention.

Community consent: A situation in which community leaders give permission for community members to participate in a research study, eliminating the need for researchers to seek informed consent from individuals.

Community-engaged research: A mechanism to involve members of the community in the planning and execution of research, inclusive of those who will be affected by or who are in a position to influence the course of research.

Community engagement: The process of working collaboratively and engaging actively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the wellbeing of those people. [Adapted from *Principles of Community Engagement*, Second Edition (2011)].

Distributive justice: An ethical principle that calls for equitable distribution of benefits and burdens across society—for example, the benefits and burdens of biomedical research, or of technological advances.

Informed consent: The process of informing and obtaining permission from an individual before conducting medical or research procedures or tests.

Non-maleficence: An obligation on the part of researchers not to cause intentional harm to research participants.

Protocol: A plan for the conduct of a research project, including all aspects of the project from recruitment to obtaining informed consent to dissemination of results.

Respect for persons: Ethical principle requiring that individuals are treated as independent and self-determining (autonomous) agents and that persons with diminished autonomy are entitled to additional protections.

IX. Additional Resources

Bierer, B.E., Chair, Secretary's Advisory Committee on Human Research Protections (SACHRP). (2011). Comments submitted to the Presidential Commission for the Study of Bioethical Issues (PCSBi), August 5. Retrieved from <http://www.hhs.gov/ohrp/sachrp/commsec/commentspcsbi.pdf.pdf>.

Clinical and Translational Science Awards Consortium and Community Engagement Key Function Committee Task Force on the Principles of Community Engagement. (2011). *Principles of Community Engagement, Second Edition*. Bethesda, MD: NIH. Retrieved from <http://www.atsdr.cdc.gov/communityengagement/>.

Horowitz, C.R., et al. (2009). Community-based participatory research from the margin to the mainstream: Are researchers prepared? *Circulation*, 119(19), 2633-2842.

Mills, E.J., et al. (2005). Designing research in vulnerable populations: Lessons from HIV prevention trials that stopped early. *British Medical Journal*, 331(7529), 1403-1406.

Presidential Commission for Study of Bioethical Issues (PCSBi). (2011, September). *Research Across Borders: Proceedings of the International Research Panel of the Presidential Commission for the Study of Bioethical Issues*, pp. 50-53. Washington, DC: PCSBi.

UNAIDS/AVAC. (2011). *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials 2011, Second Edition*. Geneva: UNAIDS. Retrieved from http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC1853_GPP_Guidelines_2011_en.pdf.

Warren, M., Executive Director, AVAC: Global Advocacy for HIV Prevention. (2011). Community Engagement—Needs, Models and U.S. Actions. Presentation to the Presidential Commission for the Study of Bioethical Issues (PCSB), August 29. Retrieved from <http://bioethics.gov/node/319>.